IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

JANNES et al

Atty. Ref.: **2551-58**

Serial No. **09/787,000**

Group: **1648**

Filed: **March 13, 2001**

Examiner: **Foley**

For: **IDENTIFICATION OF MICROORGANISMS CAUSING ACUTE RESPIRATORY TRACT INFECTIONS (ARI)**

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March 14, 2002

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

RESPONSE

Responsive to the Official Action dated January 15, 2002, the applicants elect, with traverse, the subject matter of the Examiner's Group I for further prosecution in the above.

Reconsideration and withdrawal of the restriction requirement, and especially the requirement for further election of "one primer from Tables 2 and 4 for each of the required regions in claim 1 and ... one probe from Tables 3, 4, or 5." See, page 2 of the Office Action dated January 15, 2002 (Paper No. 6).

In the event the restriction requirement is maintained, the Examiner is requested to indicate where the PCT rules allow for the requirement of election of one primer and one probe, as required by the Examiner. Specifically, the Examiner's stated basis (i.e., that the primers and probes "are structurally unique and are used for functionally different purposes of amplifying and/or detecting structurally and functionally unrelated products") is the basis often used for requiring such a restriction in regular U.S. utility

applications which do not derive from international PCT filings. The Examiner is urged to appreciate that the present application enjoys the benefit in this regard of being a 371 application of PCT/EP99/07065 and the PCT unity of invention requirements apply.

Consideration of the following with regard to the restriction requirement is requested.

The applicants urge the Examiner to appreciate that the presently claimed invention provides methods of simultaneous detection of different organisms responsible for respiratory tract infections. The inventive concept is based on the fact that different gene regions have been identified or selected (i.e., discovered), as recited in the claims, in which primers have been designed, with the aim of allowing simultaneous amplification.

The different combinations of primers designed in the recited regions are suitable for such a purpose. The Examiner's requirement to limit the claimed invention and/or examination of the invention based on specific sequences is contrary to the claims and disclosure. Moreover, the Examiner's requirement may likely limit the applicants' ability to generically protect their disclosed invention. The applicants have disclosed the presently claimed invention with the intent of receiving the limited monopoly of patent protection, to the extent the invention is patentable over any prior art and is supported by an enabling disclosure, for example, The Examiner's further apparent requirement however to limit the extent of protection obtainable is less than the *quid pro quo* envisioned by the patent system is improper.

Therefore, to the extent that claims 1 to 3 (i.e., the pending generic claims of Group I) are new and inventive, the applicants should be able to claim, receive an examination of, and protect all possible primer combinations that allow simultaneous amplification, and not only one specific primer combination. Withdrawal of the Examiner's requirement of an election of one primer is requested.

The Examiner's requirement for election of one primer is not understood as primers in Tables 2 and 4 are, with one exception, provided as primer pairs, as would be understood by one of ordinary skill in the art. The exception noted above is with regard to Mycoplasma pneumoniae for which 2 forward primers are provided in Table 4 (SEQ ID NOs:17 and 18). The Examiner is urged to appreciate that in the amplification process, the primers work in pairs. Moreover, examination of the specifically disclosed primer pairs would not be an undue burden on the Examiner.

Withdrawal of the requirement to elect one primer is requested. To be responsive only, the applicants elect the pair of SEQ ID NOs:17 and 18 and, as one primer, SEQ ID NO:18.

Concerning the requirement to elect one probe, the Examiner is requested to consider the following and withdraw the requirement.

The applicants assume that the Examiner is requiring election of one probe for each of the organisms mentioned in claim 1 and not only one single probe, as otherwise the aim of the invention to detect simultaneously the different organisms recited in the claims, could not permit the stated purpose of the claimed invention. Clarification is requested in the event the applicants have misunderstood the requirement.

As already mentioned, the claimed invention provides for the simultaneous detection of different organisms responsible for respiratory tract infection, and only the use of a combination of primers (primer sets) and a combination of probes (when the detection is performed by using probes) may allow solution of this problem.

Contrary to the Examiner's assertions, the primers and the probes are structurally related, and they are used for structurally and functionally related products. Accordingly, the Examiner's basis for requiring the election is not correct.

It may be true that primers and probes are used for functionally different purposes: respectively, the former are used for amplifying and the latter for detecting. In the method of claim 5, however, for example, they are not used for unrelated products.

Indeed, the probes are specifically designed for detecting the amplified sequences (the products of the amplification step). In other words, both primers and probes have common target sequences, which are the regions recited in the more generic claims 1 to 3.

Furthermore, to be able to detect strains of a same organism, it may be more efficient, and sometimes recommended, to use two different probes. This is the case, for example, for SEQ ID NO:8 and SEQ ID NO:9: some Adenovirus strains will react with (and then be detected by) the first probe and not with the second, some will react with both and some will react with the second one only.

The following probes are provided for each region to be detected: Enterovirus (SEQ ID NO:4), Influenza A (SEQ ID NO:5), Influenza B (SEQ ID NO:6), Parainfluenza

3 (SEQ ID NO:13), Mycoplasma pneumoniae for the rRNA region (SEQ ID NO:15), Chlamydia pneumoniae for the rRNA region (SEQ ID NO:16), Bordetella pertussis (SEQ ID NO:29) and Bordetella parapertussis/bronchiseptica (SEQ ID NO:30).

The restriction requirement relating to election of a single probe should be withdrawn.

For the purpose of being responsive only, the applicants elect the following probes: SEQ ID NO:8, SEQ ID NO:11, SEQ ID NO:26, and SEQ ID NO:28.

Withdrawal of the restriction requirement and an Action on the merits of all the claimed subject matter is requested.

Respectfully submitted,

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By: _____

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